

REMARKS

I. Summary Of Examiner's Action

The Examiner withdrew non-elected claims 13-17 and 21-49.

The Examiner withdrew elected claims 22-26 on the basis that those claims did not read upon the species elected by applicants.

Claim 18 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the term "expandable membrane."

Claims 1-12 and 18-20 were rejected under 35 U.S.C. § 102(e) as being anticipated by Lesh et al. U.S. Patent No. 6,152,144 (hereinafter "Lesh").

II. Applicants' Response

Applicants include herein a reply to the Office Action. Reconsideration and allowance of this application in light of the following remarks are respectfully requested.

A. The Rejection Based On 35 U.S.C. § 112, Second Paragraph

Applicants have amended claim 18 to further distinctly claim the invention.

B. The Rejection Based On 35 U.S.C. § 102(e)

Applicants respectfully traverse the Examiner's rejection. The Examiner argues that col. 1, lines 64-67 and col. 2, lines 1-67 of Lesh describe all the elements of claims 1 and 18, including the claimed filter feature. The

Examiner also argues that Figures 6-7 and 9 of Lesh illustrate all of the claimed elements, including the claimed filter feature. Applicants will address each of the Examiner's arguments separately.

1. Lesh's Written Description Does Not Disclose An Open-Channeled Filter Feature

The Examiner argues that col. 1, lines 64-67 and col. 2, lines 1-67 of the Lesh patent contain all elements described in applicants' claims 1 and 18, including the claimed filter feature. However, there simply is no evidence of a filter feature in Lesh's written description. In fact, Lesh states exactly the opposite. The function of the Lesh device is to create a complete and immediate seal against fluids and blood. To illustrate, Lesh says in col. 2, lines 33-35 that "[t]he frame structure has a barrier or mesh material disposed over it and preferably secured to it to act as a barrier to the passage of embolic material or fluids." (Emphases added.) Lesh reiterates in col. 2, lines 39-41 that "[t]he mesh or barrier material can be any suitable material for preventing the passage of fluids, embolic material or other material suspended in fluids." (Emphasis added.) Lesh neither teaches nor suggests in the specification a filter feature for allowing the passage of fluids, blood or gases.

Although Lesh says that the polymeric biomaterials making up the barrier/mesh may contain pores, applicants distinguish pores from open channels on page 13, lines 8-18 of their specification. ("The term pore refers to a small cavity in the material of a filter element. Cavities or pores do not provide a continuous open channel or passageway

through the filter element. Partially opened surface pores, however, are an important component of surface texture which is advantageous for cellular tissue ingrowth.").

In contrast to Lesh, applicants' disclose continuous open channels through the porous membrane of the biomaterials and further suggest techniques for drilling such open channels. ("[F]or filter elements made of solid sheet material, other techniques such as laser drilling may be used for making small diameter holes." See page 24, lines 16-18 of applicants' specification.) In sum, Lesh's references to pores on the surface of the biomaterials must not be confused with the applicants' disclosure of open-channeled filters for blood, liquid and gas to flow through.

2. Lesh's Figures Do Not Illustrate An Open-Channeled Filter Feature

Contrary to the Examiner's assertion, the device shown in Figures 6-7 and 9 of the Lesh patent does not in any way embody the above-described advantageous filter feature of applicants' claimed invention. The Examiner asserts that structure 63 of the Lesh device discloses a filter feature. However, applicants wish to emphasize that Lesh describes structure 63 of Fig. 6 as a barrier, not as an open channel for filtration. This is expressly stated in col. 9, line 17 of Lesh. In describing the features of barrier 63, Lesh refers to the corresponding embodiments depicted in Figs. 1-5, presumably barrier 15. See Col. 9, lines 39-42. Lesh describes in col. 7, lines 47-49 that barrier 15 is a thin mesh or film of material which serves to block the passage of material within an area. (Emphasis added.) Moreover, applicants wish to draw the Examiner's attention to the

entirety of Lesh's Detailed Description of the drawings where Lesh neither teaches nor suggests that barrier 15 or barrier 63 serve as an open-channeled filter.

C. Significance of Applicants' Open-Channeled Filter Feature

The Examiner may not have fully appreciated the structural significance of applicants' filter feature. The atrial appendage collects blood and contracts ("beats") along with the rest of the heart. One advantage of applicants' filter feature is to prevent an immediate change in blood pressure and blood flow in the vicinity of the implant after it has been implanted. By making their device a filter rather than a plug, applicants reduce the pressure gradient across their implant, thereby reducing the likelihood that their device will be ejected from the beating atrial appendage. Further, no sudden pressure change occurs during the acclimatization period as tissue gradually grows over the holes and pores of the device. Applicants repeatedly emphasize throughout their application the advantageous nature of the filter feature, even titling the application "EXPANDABLE IMPLANT DEVICES FOR FILTERING BLOOD FLOW FROM ATRIAL APPENDAGES." (Emphasis added.) Thus, the Examiner should recognize the significance of applicants' novel filter feature.

For at least the foregoing reasons, the Lesh patent does not teach or suggest a feature for filtering blood, fluids and gases that continue to flow between the atrial appendage and the associated atrium of the heart after the device has been implanted. Claims 1 and 18 are therefore allowable over Lesh. The same is true for claims 2-12 and

Appl. No. 09/932,512

Amendments & Reply to Office Action dated December 24, 2003

19-20 because these two claim groups depend from claim 1 and amended claim 18, respectively.

III. Conclusion

For at least the reasons stated above, applicants respectfully submit that this application, which includes claims 1-12, 18-20, is in condition for allowance. Reconsideration and a favorable action are respectfully requested.

Respectfully submitted,



Robert R. Jackson
Reg. No. 26,183
Attorney for Applicants

Asheesh P. Puri
Reg. No. 53,494
Attorney for Applicants
FISH & NEAVE
Customer No. 1473
1251 Avenue of the Americas
New York, New York 10020-1105
Tel.: (212) 596-9000
Fax: (212) 596-9090